

REMARKS

Reconsideration of the above-identified application in view of the proposed amendment above and the remarks below is respectfully requested.

Claims 1-4, 36 and 39 are herein proposed to be canceled. No claims are herein proposed to be amended or added. Therefore, claims 5-19, 21-30, 32-35 and 37-38 are pending. Of these claims, claims 12, 16, 29 and 32-33 have been "withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim." Accordingly, claims 5-11, 13-15, 17-19, 21-28, 30, 34-35 and 37-38 are under active consideration.

Claim 1 stands rejected under 35 U.S.C. 102(b) "as being clearly anticipated by Bonaldo, US 5,947,954"; claims 1-3 stand rejected under 35 U.S.C. 102(b) "as being clearly anticipated by Steer, US 4,603,837"; claims 1-3 stand rejected under 35 U.S.C. 102(b) "as being anticipated by French et al., US 6,095,997"; and claims 1-3, 36 and 39 stand rejected under 35 U.S.C. 103(a) "as being unpatentable over Kelliher '924 in view of Delegge '901." Without acquiescing in the propriety of the foregoing rejections, Applicants have canceled claims 1-3, 36 and 39. Therefore, the foregoing rejections are now moot and should be withdrawn.

Claims 5-10, 17-24, 27-28, 30 and 34-35 stand rejected under 35 U.S.C. 103(a) "as being unpatentable over Kelliher '924 in view of Dennehey et al., US 4,417,890." In support of the rejection, the Patent Office states the following:

The only difference between Kelliher and the claimed invention is that applicant now claims that the front end of the stem is enclosed in the housing. In other words, the shape of housing 17 is such that it encloses the connection of the stem. It is well established that changes in shape or size are prima facie obvious in the lack of a showing of criticality. See MPEP 2144.04, IV. B.,

entitled, "Changes in Shape." Applicant's specification does not assert any unusual feature resulting from the expanding [of] the housing so that it encloses the front end of the stem, accordingly, these claims must be rejected. Dennehey is cited to exemplify that recessing a medical connector element within a housing is generally known in the art and useful to achieve a stated purpose (having a cap) if desired. In the alternative, a connection element can be extended out of a housing so that it can be cleaned easier, for example. Each design (Kelliher and applicant's) is different, and each has benefits and drawbacks that are well known in the art and expected.

Insofar as the subject rejection pertains to claim 20, the rejection is in error since claim 20 was canceled in a previous amendment. Insofar as the subject rejection pertains to claims 6-10, 17-19, 21-24, 27-28, 30, 34 and 35, Applicants respectfully traverse the subject rejection.

Claim 5, from which claims 6-10, 17-19, 21-24, 27-28, 30, 34 and 35 depend, recites "[a]n adaptor well-suited for use with a medical catheter, said adaptor comprising:

(a) a body, said body being provided with a first channel and a second channel, said first channel and said second channel being in fluid communication with one another, said first channel being adapted for fluid communication with the medical catheter, said second channel having a front end; and

(b) a stem, said stem having a front, a rear, a side wall, a cavity extending rearwardly from said front end, and a hole in said side wall in fluid communication with said cavity, said stem being mounted within said second channel of said body with said front end of said stem being spaced rearwardly from said front end of said second channel, said stem being rotatable between an open position in which said stem and said first channel are in fluid communication with one another via said hole and a closed position in which said stem and said first channel are not in fluid communication with one another."

The Patent Office apparently concedes that the claimed adaptor differs from the feeding apparatus of Kelliher et al. in that Kelliher et al. does not teach or suggest an adaptor well-suited for use with a medical catheter wherein the adaptor comprises (i) a body provided with first and second channels, the second channel having a front end, and (ii) a stem rotatably mounted in said second channel, the stem having a front end spaced rearwardly from the front end of the second channel. Nevertheless, despite the lack of this teaching in Kelliher et al., the Patent Office counters by contending that it would have been obvious to modify the Kelliher apparatus so that its valve assembly 14 is spaced rearwardly from the front end 24 of its external retention portion 18 since “changes in shape or size are *prima facie* obvious in the lack of a showing of criticality.” The Patent Office then refers to Dennehey et al. as exemplifying that “recessing a medical connector element within a housing is generally known in the art and useful to achieve a stated purpose (having a cap) if desired.” For the reasons below, Applicants respectfully disagree with the Patent Office’s reasoning and with its conclusion of obviousness.

First, Applicants wish to point out that it is the Patent Office who bears the burden of proving that the claimed invention is *prima facie* obvious over the prior art - Applicants, by contrast, do not bear the burden of disproving the opposite proposition, namely, that the claimed invention is unobvious. Consequently, in the absence of the Patent Office meeting its burden, Applicants need not come forward with a showing of criticality or otherwise.

Second, to the extent that the Patent Office has attempted to make its *prima facie* case of obviousness simply by characterizing the differences between the claimed invention and the Kelliher apparatus as merely a “change in shape or size” and then referring to MPEP 2144.04, IV.B as

justification for finding such differences obvious, Applicants respectfully submit that the Patent Office has erred and, therefore, failed to meet its burden.

As noted above, a difference between the claimed invention and Kelliher et al. is that the claimed invention includes a stem having a front end that is spaced rearwardly from a front end of a second channel whereas, in Kelliher et al., valve assembly 14 extends forwardly beyond the front end 24 of its external retention portion 18. Applicants respectfully submit that such a difference between the claimed invention and the prior art represents a significant departure from the prior art and is not simply a “change in shape” of the type referred to in MPEP 2144.04, IV.B. In fact, MPEP 2144.04, IV.B provides as follows:

In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.).

It can readily be appreciated that, if one were to take the Patent Office’s analysis to its logical conclusion, nearly any apparatus would be rendered obvious over related prior art as one could merely state that each difference between the two merely represented a “change in shape.” Clearly, this is not the correct outcome, and a “change in shape” argument should not be applied to differences of the type present in this case.

Moreover, Kelliher et al., itself, clearly teaches away from the types of modifications that would be necessary to arrive at the prior art. For example, one of the principal features of the Kelliher et al. apparatus is that its valve assembly be capable of being switched, **using a person’s fingers**, between an open position and a closed position. (See e.g., col. 3, lines 58-60 of Kelliher et al., which provides “[i]n the present invention, the mechanism is an externally applied force which

is a person's fingers rotating the valve.") Clearly, if one were interested in permitting digital manipulation of the Kelliher valve, one would not want to modify the Kelliher apparatus so that its valve is recessed relative to its main retention portion since this would make access to the valve and its rotation more difficult.

Unlike Kelliher et al., Dennehey et al. is not directed at a feeding apparatus, but rather, is directed at a connector used in peritoneal dialysis procedures. In addition, unlike Kelliher et al., the Dennehey device does not have a rotatable valve; consequently, the issue of valve manipulation using one's fingers that is key to Kelliher et al. is completely absent in Dennehey et al. Moreover, the whole rationale given by Dennehey et al. for the construction of its device, namely, to permit the front end of its connector to be bathed in an antiseptic solution, would be recognized by one of ordinary skill in the art as unnecessary for the Kelliher feeding apparatus. Consequently, Dennehey et al. would not be recognized by one of ordinary skill in the art as providing any motivation to modify the Kelliher et al. apparatus.

Therefore, for at least the above reasons, claim 5 is patentable over Kelliher et al. in view of Dennehey et al.

Claims 6-10, 17-19, 21-24, 27-28, 30 and 34-35 depend from claim 5 and are patentable over Kelliher et al. in view of Dennehey et al. for at least the same reasons given above for claim 5. In addition, claim 10 is further patentable over the applied references for the reason that the references do not teach or suggest the desirability of securing the feeding apparatus to a medical catheter or means for effecting the same, and claim 24 is further patentable over the applied references for the reason that the references do not teach or suggest shaping the exterior of the side wall of the stem to include a stop block and shaping the second channel to include a pair of stop surfaces, said stop

block being engageable with said stop surfaces in such a way as to limit the range of rotation of said stem between said open and closed positions.

Accordingly, for at least the above reasons, the subject rejection should be withdrawn.

Claims 11, 13-15 and 36-38 stand rejected under 35 U.S.C. 103(a) “as being unpatentable over Kelliher ‘924 and Dennehey ‘890 as applied to claim 10 above, and further in view of Delegge, ‘901.” In support of the rejection, the Patent Office states the following:

Kelliher and Dennehey disclose all of the claimed embodiments except for the ring-shaped member to secure the medical catheter. Kelliher discloses a one-piece bolster/valve apparatus with the bolster (Kelliher balloon 48) integrally connected to the valve 12. Applicant calls for a two-piece apparatus using a ring-shaped member to connect the bolster. Delegge exemplifies that ring-shaped securing members are well known in two-piece apparatuses. Accordingly, it would be obvious to one of ordinary skill in the art to attach a ring shaped member to make the Kelliher apparatus separable instead of integral. Regarding the claimed step increases for the outer diameter of the lower portion, it appears that Delegge discloses these features for optimally attaching the ring securement device.

Applicants respectfully traverse the subject rejection. Claims 11, 13-15 and 37-38 depend directly or indirectly from claim 5. Claim 5 is patentable over Kelliher et al. and Dennehey et al. for at least the reasons discussed above. DeLegge fails to cure all of the deficiencies of Kelliher et al. and Dennehey et al. with respect to claim 5. Therefore, based at least on their respective dependencies from claim 5, claims 11, 13-15 and 37-38 are patentable over the applied combination of Kelliher et al., Dennehey et al. and DeLegge. In addition, claims 13-15 are further patentable over the applied combination of references for at least the reason that Kelliher et al., Dennehey et al. and DeLegge, taken individually or in combination, do not teach or suggest at least one step of increasing outer diameter on top of said tube support. DeLegge, contrary to the Patent Office’s

assertion, does not disclose a step of increasing outer diameter on top of a tube support, but rather, only discloses a threaded fitting 16. No steps are shown above DeLegge threaded fitting 16.

Furthermore, Applicants respectfully submit that there is no basis for combining Kelliher et al., Dennehey et al. and DeLegge in the manner proposed by the Patent Office. As explained above, Kelliher et al. is directed at a feeding apparatus that includes a flexible feeding tube (40/140) having an internal retention balloon (48/148). There would have been no reason for one of ordinary skill in the art to have attached another feeding tube to the distal end of flexible feeding tube (40/140) using a nut or other securing device. In addition, to the extent that the Patent Office appears to be arguing that it would have been obvious to modify the Kelliher feeding apparatus from a “one-piece bolster/valve apparatus” to a two-piece apparatus, Applicants respectfully disagree. The balloon bolster of Kelliher is inextricably integrated into the design of the Kelliher apparatus. In order to convert the Kelliher apparatus to a two-piece apparatus, one would need to drastically re-design the Kelliher apparatus.

Finally, claim 36 is patentable over the applied combination of references for at least the same types of reasons discussed in the previous paragraph.

Accordingly, for at least the above reasons, the subject rejection should be withdrawn.

Claims 25 and 26 stand rejected under 35 U.S.C. 103(a) “as being unpatentable over Kelliher ‘924 and Dennehey ‘890 as applied to claim 5 above, and further in view of Shmulewitz et al., US 6,569,145.” In support of the rejection, the Patent Office states the following:

Kelliher and Dennehey disclose all of the claimed embodiments except for the window 53 to permit viewing of the valve position. Shmulewitz discloses that it is known to use a window 60 to show the position of a valve structure. See figures 5A, 5B, and column 7, line 8 of Shmulewitz. Accordingly, it would have been obvious to one of ordinary skill in the art to attach a window to

the Kelliher apparatus so that it would have been visually apparent if the valve were open or closed as shown by Shmulewitz, for the purpose of confirming the valve position.

Applicants respectfully traverse the foregoing rejection. Claims 25 and 26 depend from claim 5. Claim 5 is patentable over Kelliher et al. and Dennehey et al. for at least the reasons discussed above. Shmulewitz et al. fails to cure all of the deficiencies of Kelliher et al. and Dennehey et al. with respect to claim 5. Therefore, based at least on their respective dependencies from claim 5, claims 25 and 26 are patentable over the applied combination of Kelliher et al., Dennehey et al. and Shmulewitz et al.

Moreover, there is no basis for combining Kelliher et al., Dennehey et al. and Shmulewitz et al. in the manner proposed by the Patent Office. Kelliher et al., as noted above, is directed at a feeding apparatus. Shmulewitz et al., by contrast, is directed at a pressure-controlled continuous coronary sinus occlusion device. The valve structure of Shmulewitz et al. is entirely different from that of Kelliher et al. Moreover, whereas the Kelliher valve structure is disposed at the proximal end of the Kelliher feeding apparatus and is, therefore, easy to observe by an operator, the Shmulewitz valves 57a-57c are disposed at the distal end of the Shmulewitz occlusion device and are, therefore, difficult to observe by an operator. In view of these stark differences between the Kelliher and Shmulewitz devices, the Patent Office has failed to explain (i) why one of ordinary skill in the art would have been motivated to modify the Kelliher device to include a window and (ii) how the Kelliher device would have been modified to include such a window.

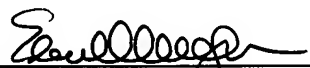
Accordingly, for at least the above reasons, the subject rejection should be withdrawn.

In conclusion, it is respectfully submitted that the present application is now in condition for allowance. Prompt and favorable action is earnestly solicited.

If there are any fees due in connection with the filing of this paper that are not accounted for, the Examiner is authorized to charge the fees to our Deposit Account No. 11-1755. If a fee is required for an extension of time under 37 C.F.R. 1.136 that is not accounted for already, such an extension of time is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

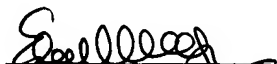
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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 14, 2005.



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